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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,532	01/30/2004	Robert G. Whirley	1880-17 RCE III	8638

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Hoffmann & Baron LLP
6900 Jericho Turnpike
Syosset, NY 11791

EXAMINER	
SWEET, THOMAS	
ART UNIT	PAPER NUMBER
3774	
MAIL DATE	DELIVERY MODE
05/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/769,532	WHIRLEY ET AL.	
	Examiner	Art Unit	
	Thomas J. Sweet	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-14,18,19,21,36,39 and 41-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-14,18,19,21,36,39 and 41-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments, see page 10, filed 01/29/2009, with respect to drawings have been fully considered and are persuasive. The objection of drawings has been withdrawn.

Applicant's arguments, see page 10, filed 01/29/2009, with respect to 35 U.S.C. 112 have been fully considered and are persuasive. The rejection under 35 U.S.C. 112 of claims 11-14 and 18 has been withdrawn.

Applicant's arguments filed 01/29/2009 have been fully considered but they are not persuasive. Regarding drug polymers, the Rhee et al passages note by applicant to not support the assertion. The passage in col 17 regards transplants and patient tissue such as a wound and merely state it is a preferred embodiment. However, the graft citation in col 18 could be an artificial graft (i.e. artificial blood vessel or stent/graft also listed). Nothing in these passages suggests that the drug polymer must be in contact with tissue when on an artificial graft. The Rhee et al reference also supported the Examiner official notice that it is well known that Polyethylene glycol is art type of polyethylene glycol and to use a host biodegradable polymer to contain bioactive materials for the purpose of sustained release over time. This is now admitted prior art since the official notice was not addressed. One of ordinary skill in the art recognizes that a drug polymer eludes from within an eluding container such as Kocur discloses since body fluids which penetrate the container activate the drug polymer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 11-14, 18-19, 21, 36, 39 and 41-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kocur et al (2002/0103527) in view of Chobotov (WO 99/39662) and Rhee et al (6051648). Kocur et al discloses a graft (fig. 1A) comprising: a graft body 10 section having a proximal end, a distal end, and defining at least one inflatable porous channel 15; a connector member affixed to the proximal or distal end of the graft body section (abstract, "attached" inherently include one or more connector elements such as the disclosed adhesive or weld/fuse), the connector member comprising one or more connector elements; a stent comprising one more proximal stent connector elements coupled to the one or more connector member connector elements (abstract),and an inflation medium including at least one therapeutic agent (abstract) configured to be introduced into the inflatable channel. However, Kocur et al remains silent as to a channel configuration such as at least one inflatable porous axisymmetric cylinder cuff (in as much as applicant's is disclosed) the graft body section and in fluid communication with the at least one channel. Chobotov discloses another graft including a channel configuration such as at least one inflatable axisymmetric cylinder cuff disposed at the proximal 11 and distal end 12 of the graft body section and in fluid communication with the at least one channel 13 for the purpose of supporting the graft and sealing it to the wall. It would have been obvious to one of ordinary skill in the art at the time the invention was made to configure the channels of Kocur et al in the configuration of at least one inflatable porous axisymmetric cylinder cuff disposed at the proximal and distal end of the graft body section and in fluid communication with the at least

one channel as taught by Chobotov in order to support and seal the graft to the wall. It is now admitted prior art that Polyethylene glycol is art type of polyethylene glycol used for drug delivery and evidenced by it disclosure in the Rhee et al reference (background of the invention). Kocur et al also remains silent as to the use of a host polymer for containing the bioactive materials. It is admitted prior art in the art of stents to use a host biodegradable polymer to contain bioactive materials for the purpose of sustained release over time. Rhee et al demonstrates the use of host polymer (polyethylene glycol, a curable liquid) for containing bioactive material(s) in conjunction with a graft (col 18, line 21). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize polyethylene glycol as a bioactive delivery material in the graft of Kocur et al in order to sustained release over time. Such a modification amounts to mere substitution of one functionally equivalent bioactive delivery material for another within the art of grafts.

With respect to claim 4, the porous channel has varying levels of porosity ([0062]).

With respect to claims 5 and 6, the graft body section comprises expanded polytetrafluoroethylene ([0054]).

With respect to claims 7 and 8, Kocur et al discloses a graft as discussed above including one of the objects of the Kocur et al reference is to tune release quantities and times (the full disclosure), therefore it would be inherent and would be fully capable of releasing agent into the body lumen ranges from about 10 micrograms to about 100 milligrams and transport into the body lumen in a time period ranging from about seven days to about twelve months.

With respect to claims 9, 48 and 56, the at least one therapeutic agent comprises one or more agents selected from the group consisting of an endothelialization promoting agent, an

angiogenesis promoting agent, an anti-thrombotic agent, an anti-aneurysmal agent, an anti-infection agent, an anti-inflammatory agent, an anti-restenosis agent, a chemotherapeutic agent, and an anti-cancer agent (several are listed [0037]-[0051]).

With respect to claim 13, the graft body section would inherently and would be fully capable of inhibiting transport of a bulk of the host polymer, since it is the same material disclosed by the applicant.

With respect to claim 14, the host polymer is fully capable of being introduced into the inflatable channel before, during, or after graft deployment or implantation, since it is initially a liquid, which is injectable.

With respect to claim 18, polyethylene glycol is a curable liquid which would inherently and would be fully capable of a cure time ranging from about three minutes to about twenty minutes and a post-cure elastic modulus ranging from about 50 psi to about 400 psi, since it is the same material disclosed by the applicant.

With respect to claim 19, the channel comprises one or more features selected from the group consisting of helical spirals, longitudinal channels, and circumferential rings (figs. 1-5).

With respect to claims 21 and 39, Kocur et al does not disclose the stent as seen in figures 3a and 3b which have the "multi-crown configuration" and covered as in figures 1-2 as described in [0029]. Additionally, Chobotov also has the stent and connector configuration as claimed.

With regard to claims 43 and 51, neither Kocur et al or Chobotov disclose a twelve-apex configuration. However, this modification merely amounts to a change in size and shape which is not patentably distinguishable from the prior art of Kocur et al or Chobotov.

With regard to claims 44-46 and 52-55, Kocur et al has 3 and 6 crown portions along its length.

With regard to claim 47, each section of Kocur et al can be considered a stent or connector, so several stent and connectors are disposed along the graft length including the ends.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:45am - 5:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas J Sweet/
Primary Examiner, Art Unit 3774